K090959

APPENDIX 5

510(k) Summary
(As required by 21 CFR 807.92(a))

DEC 24 2009

A.	Submitter Information	D'Antonio Consultants International, Inc. (DCI, Inc.) 6308 Fly Road East Syracuse, NY 13057 Telephone: (315) 463-4999 Fax: (315) 463-5267
B.	Device Information	
	Trade/Proprietary Name:	LectraJet® Needle-Free Injection System, LectraJet®
	Common Name:	Needle Free Injector, Jet Injector
	Classification Name:	Jet Injector, Non Electrically Powered Fluid Injector
	Predicate Device:	Biojector 2000®, K960373 Medi-Jector Vision® K962956
	Device Description:	The components of the LectraJet® Needle-Free Injection System include the needle-free single-use syringes with disposable vial adapter and cap with plunger rod attached and the injector handpiece with manual reset mechanism. The LectraJet® handpiece and reset mechanism are sold as a complete injection system contained within a carrying case. The carrying case is an accessory of convenience that provides for portability, organization, and ease of use for the practitioner. The LectraJet® syringes are packaged sterile and designed to be filled by the end user at the time of use. The polycarbonate syringes have a molded orifice at the front end. The syringe orifice is available in sizes 0.006", 0.008", 0.010" and 0.012" diameter, which allows the user to choose the syringe appropriate for the desired depth of penetration (IM/SQ) and patient selection (child/adult). The syringes have a flange at the back end that is held by the injector handpiece when delivering the injection. Syringes are designed to be used immediately upon filling, similar to a traditional needle and syringe, and identical to the Biojector 2000® and Medi-Jector Vision® syringe filling philosophy. After the syringes are filled, they are inserted directly into the LectraJet® handpiece.

		The LectraJet® handpiece contains a spring drive system that, when compressed, provides the energy to deliver the injection. To compress the spring, the handpiece is placed in a manual reset mechanism and hand pressure is applied to the reset mechanism lever. In the Medi-Jector Vision®, the manual power source used to compress the spring is a hand-twist knob. In the Biojector 2000®, the power source is either a gas cartridge or a gas cylinder. When the LectraJet® handpiece is actuated, the spring drive system is released, and the handpiece ram contacts the syringe piston to drive the injectate out through the syringe orifice, creating a jet stream with enough energy to penetrate the tissue. This is identical in principle to the Biojector 2000® and the spring powered Medi-Jector Vision®. After the injection, the used syringe is released into an appropriate trash container. Little maintenance is required for the LectraJet® handpiece. There are no o-rings or seals to change. No sterilization of the handpiece is required. All of the above features are similar to the Biojector 2000® and the Medi-Jector Vision®, predicate devices and accessories.
	Intended Use:	The LectraJet Needle-Free Injection System is intended to deliver subcutaneous (SQ) or intramuscular (IM) injections of vaccines and other injectable medications. The LectraJet Needle-Free Injection System may be used by physicians, nurses, veterinarians, podiatrists and other practitioners who routinely administer injections. The LectraJet Needle-Free Injection System may also be used by patients to self inject or to have other individuals administer injections of prescribed medications. The intended use of the LectraJet® is substantially the same as the Biojector2000® and the Medi-Jector Vision®.
C.	Comparison of Required Technological Characteristics:	**Injection Force Profile:** The force profile is a measure of the force of the injection stream. The injection stream is directed at a force sensor, which measures the amount of force of the impinging injection stream. The test is used as both a comparative test (one device versus another) and as a way to evaluate the consistency of performance of an individual device.

		Injection Duration: The injection duration is the time extent of the injection from start to finish and is obtained by injecting onto a force sensor held just in front of the syringe orifice. Injection start is defined as the time point when the force measured by the force sensor rises sharply. Injection finish is defined as the time point when the force on the force sensor falls sharply. **Depth and Dispersion of Jet Stream into Homogeneous Substrate:** The depth and dispersion of the jet stream is determined by giving an injection of a standardized colored injectate into a homogeneous foam substrate. The injectate is allowed to dry in the foam, and the foam is then sliced open to measure the depth and dispersion of the injectate.
D.	Summary and Conclusion of Non Clinical and Clinical Testing	**Conclusions of the following tests:** • **Injection Force Profile:** The injection force profile for the LectraJet® is substantially equivalent to that of the Biojector 2000® and the Medi-Jector Vision®. • **Injection Duration:** The injection duration for the LectraJet® is substantially equivalent to that of the Biojector 2000® and the Medi-Jector Vision®. • **Depth and Dispersion:** Depth and dispersion of injections into a homogeneous substrate indicate that the LectraJet® performance is substantially equivalent to the performance of the Biojector 2000® and the Medi-Jector Vision® • **ISO EN 10993 –1:2003** Biocompatibility testing per ISO 10993-1:2003 will be completed prior to product launch.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Joseph P. D'Antonio
Vice President of Business Development
D'Antonio consultants International, Incorporated (DCI)
6308 Fly Road
East Syracuse, New York 13057

DEC 24 2009

Re: K090959
Trade/Device Name: LectraJet Needle Free Infection System
Regulation Number: 21 CFR 880.5430
Regulation Name: Nonelectrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: November 20, 2009
Received: December 1, 2009

Dear Mr. D'Antonio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: LectraJet Needle Free Injection System

Indications For Use:

The LectraJet Needle-Free Injection System is intended to deliver subcutaneous (SQ) or intramuscular (IM) injections of vaccines and other injectable medications.

The LectraJet Needle-Free Injection System may be used by physicians, nurses, veterinarians, podiatrists and other practitioners who routinely administer injections.

The LectraJet Needle-Free Injection System may also be used by patients to self inject or to have other individuals administer injections of prescribed medications.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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